(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 180 374 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
20.02.2002 Bulletin 2002/08

(21) Application number: **01118731.7**

(22) Date of filing: **06.08.2001**

(51) Int Cl.[7]: **A61M 1/00**, A61M 1/16, B01D 63/00, B01D 63/02, A61M 1/10, A61M 1/36

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **08.08.2000 IT MI001852**

(71) Applicant: **DIDECO S.p.A.**
I-41037 Mirandola (province of Modena) (IT)

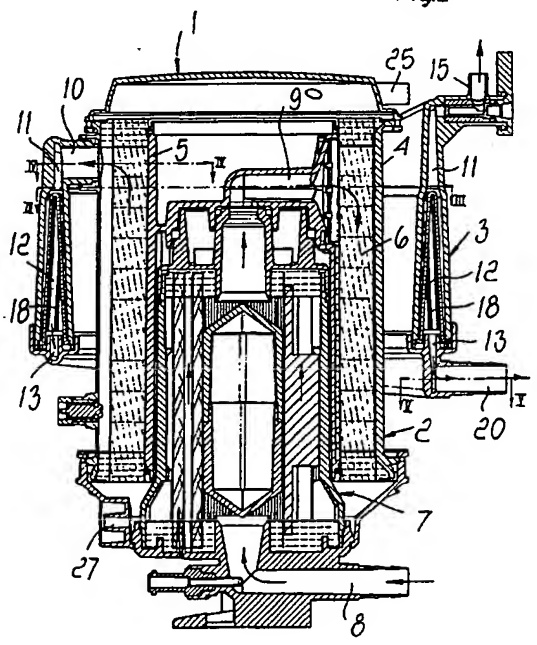
(72) Inventors:
- **Ghelli, Nicola**
  40018 S. Pietro in Casale (Bologna) (IT)
- **Costa Malanti, Edgardo**
  41037 Mirandola (Modena) (IT)
- **Panzani, Ivo**
  41037 Mirandola (Modena) (IT)

(74) Representative: **Modiano, Guido, Dr.-Ing. et al**
Modiano & Associati SpA Via Meravigli, 16
20123 Milano (IT)

(54) Device for oxygenating blood in an extracorporeal circuit

(57) A device (1) for oxygenating blood in an extracorporeal circuit includes a first structure (2) suitable to delimit a portion of space (6)-containing capillaries made of microporous membrane. The capillaries convey oxygen and are wet externally by blood flowing through a portion of space (6) between an intake connector (8), which is connected to a venous line of the extracorporeal circuit, and a delivery connector (10). The device (1) includes a second structure (3) monolithically connected and contiguous to the first structure (2). The second structure (3) is suitable to contain blood filtration means (28) that divide the portion of space delimited thereby into a blood distribution chamber (11), provided with an air vent (15) and connected to the delivery connector (10) of the first structure (2), and a blood collection chamber (13) provided with a delivery connector (10) connected to the arterial line of the extracorporeal circuit.

Fig.2



EP 1 180 374 A1

Description

[0001] This invention relates to a device for oxygenating blood in an extracorporeal circuit.

[0002] During surgery, blood flows through extracorporeal circuits. The extracorporeal circuits include an oxygenation device to transfer oxygen to the blood received from the patient by means of a line which is known as venous line and then return it to the patient by means of a line known as arterial line.

[0003] The structure of the oxygenator is such as to delimit a portion of space which contains capillaries made of microporous membrane which convey oxygen and are wet externally by the blood that flows through this portion of space. There are also oxygenators which include a heat exchanger through which the blood is meant to flow before entering the oxygenator in order to be kept at the correct temperature.

[0004] Often on the arterial line there is a filter (the arterial filter), which is meant to retain any air bubbles present in the blood in order to prevent them from remaining in the blood that returns to the patient. However, this presence can be the source of problems for operators when one considers the inherent complexity of the extracorporeal circuit in which the arterial filter is introduced.

[0005] The aim of the present invention is therefore to provide a blood oxygenation device in which the extracorporeal circuit is simplified and which offers maximum safety in preventing air bubbles from being contained in the blood that returns to the patient.

[0006] The proposed aim is achieved by a blood oxygenation device comprising a first structure suitable to delimit a portion of space which contains capillaries made of microporous membrane. The capillaries convey oxygen and are wet externally by blood flowing through the portion of space between an intake connector, which is connected to the venous line of the extracorporeal circuit, and a delivery connector. There is a second structure monolithically connected and contiguous to the first structure suitable to contain blood filtration means which divide the portion of space delimited thereby into a blood distribution chamber, provided with an air vent and connected to the delivery connector of the first structure, and a blood collection chamber which is provided with a delivery connector which is connected to the arterial line of the extracorporeal circuit.

[0007] In one aspect, this invention is a device for oxygenating and filtering blood in an extracorporeal circuit comprising a housing defining first and second interior chambers, the first chamber containing a plurality of microporous filters and having a blood inlet and a blood outlet connected to the first chamber to define a blood flow path along an exterior of the hollow fibers and having a gas inlet and a gas outlet connected to the first chamber to define a gas flow path through the lumens of the hollow fibers, the second chamber containing a filtration membrane and having a blood inlet and a blood outlet connected to the second chamber to define a blood flow path through the filtration membrane, the blood inlet of the second chamber being connected to receive blood from the blood outlet of the first chamber.

[0008] In a second aspect, this invention is an integrated device for oxygenating and filtering blood in an extracorporeal circuit, comprising an oxygenator having a housing including a top, a bottom, and a side wall together defining an oxygenation chamber containing a microporous membrane, the housing having a blood inlet and a blood outlet positioned to define a blood flow path along a first side of the microporous membrane and a gas inlet and a gas outlet positioned to define a gas flow path along a second side of the microporous membrane; and an arterial blood filter having a housing including a top and bottom, a substantially cylindrical outer wall, and a substantially cylindrical inner wall together defining a substantially ring-shaped interior chamber containing a filtration membrane, the inner wall defining a substantially cylindrical opening in the housing of the arterial filter, the housing having a blood inlet connected to the interior chamber on a first side of the filtration membrane and a blood outlet connected to the interior chamber on a second side of the filtration membrane, to define a blood flow path through the filtration membrane, the blood inlet of the arterial filter being connected to the blood outlet of the oxygenator, the housing of the oxygenator being rigidly connected to the housing of the arterial filter and positioned in the substantially cylindrical opening in the housing of the arterial filter.

[0009] In a third aspect, this invention is an integrated device for use in an extracorporeal blood circuit, comprising a housing defining a first portion and a second portion; means for oxygenating blood contained within the first portion of the housing, the oxygenating means including a blood inlet and a blood outlet; and means for filtering oxygenated blood, the filtering means having a blood inlet connected to receive blood from the blood outlet of the oxygenating means and a blood outlet.

[0010] In a fourth aspect, this invention is a monolithic device for use in extracorporeal blood circuit, comprising a housing having a blood oxygenator portion and an arterial blood filter portion, the blood oxygenator portion containing a gas exchange membrane and having a blood inlet and a blood outlet defining a blood flow path along a first side of the gas exchange membrane and having a gas inlet and a gas outlet for defining a gas flow path along a second side of the gas exchange membrane, the arterial blood filter portion containing a filtration membrane and having a blood inlet and a blood outlet defining a blood flow path through the filtration membrane, the blood inlet of the arterial blood filter portion being connected to receive blood from the blood outlet of the blood oxygenator portion.

[0011] In a fifth aspect, this invention is an arterial blood filter comprising a housing having a top surface, a bottom surfac , a substantially cylindrical outer wall and a substantially cylindrical inner wall together defin-

ing a substantially ring-shaped interior chamber, the inner wall defining a substantially cylindrical opening from the top surface to the bottom surface of the housing; a filtration membrane contained within the ring-shaped interior chamber; a blood inlet; and a blood outlet, the blood inlet and blood outlet being positioned on the housing to define a blood flow path through the housing across the filtration membrane.

[0012] Further characteristics and advantages will become apparent from the description of a preferred but not exclusive embodiment of the invention, illustrated only by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a perspective view of the blood oxygenation device of this invention.

Figure 2 is a sectional view, along a longitudinal plane, of the device shown in Figure 1.

Figure 3 is a sectional view, taken along the transverse plane III-III of the device shown in Figure 2.

Figures 4 and 5 are sectional views, taken respectively along the plane IV-IV and along the plane V-V of Figure 2.

Figure 6 is a perspective view of the filtration means with a portion of filtration membrane cut away.

Figure 7 is a perspective view of the arterial filter.

Figure 8 is a side view of the arterial filter.

[0013] With reference to the Figures 1 to 8, the numeral 1 generally designates the device, which comprises a first structure, generally designated by the reference numeral 2, and a second structure, generally designated by the reference numeral 3, which are monolithically connected.

[0014] Structure 2, which constitutes the actual oxygenator, comprises cylindrical walls 4 and 5, which are suitable to define a portion of space 6 comprising an oxygenation chamber that contains in a known manner hollow fibers or capillaries made of microporous membrane which convey oxygen through the lumens of the fibers from gast inlet port 25 to gas outlet port 27. The structure of the oxygenator is similar to that disclosed in commonly assigned U.S. Patent No. 5,817,278 (Fini et al.), which is incorporated by reference herein in its entirety. Contained within the central portion of the cylindrical oxygenator is a heat exchanger, also known, which is generally designated by reference numeral 7. The inlet to the heat exchanger includes intake connector 8 which is suitable to be connected to the venous line of an extracorporeal circuit.

[0015] Blood enters exchanger 7 through inlet 8, flows through it, and reaches the outlet 9 of the heat exchanger. The outlet of the heat exchanger includes connector 9 that leads into a portion of space 6. Blood entering space 6 through connector 9 wets from the outside the capillaries contained therein until the blood arrives, after being oxygenated, at the outlet of the oxygenator. Delivery connector 10 provides a fluid path from the outlet of the oxygenator to the inlet of structure 3. Connector 10 is located in a higher position in order to ensure the elimination of air bubbles, all as shown by the arrows in the figures.

[0016] The structure generally designated by reference numeral 3 is monolithically connected to first structure 2 described above and acts as an arterial filter. Structure 3 is annular and comprises housing 30 which defines an internal portion of space which comprises blood distribution chamber 11, intermediate region 12 which comprises filtration means 28, and blood collection chamber 13.

[0017] As shown in Figure 4, blood distribution chamber 11 is connected to connector 10 for receiving the outflow of the blood from the oxygenator at a region which is provided with crest 14 which is suitable to split the blood into two half-ring-shaped flow paths which lie on opposite sides with respect to connector 10 and extend to the diametrically opposite region, where air vent 15 is provided.

[0018] The flow path followed by each half-ring, as shown in the figures, is through the internal space defined by the housing of the arterial filter. The housing has a constant base dimension and a height which decreases from the region adjacent connector 10, and then increases to a maximum value at air vent 15 as best seen in Figure 8. The cross-sectional area of the internal space defining the blood flow passage is a function of the height of the housing. Consequently, the cross-sectional area of the internal space or blood flow passage at the inlet of the arterial filter is greater than that of the cross-sectional area at locations where the height is less than at the inlet.

[0019] This leads to a situation in which the blood, after slowing down at the inlet of structure 3, with an initial separation of any air bubbles contained therein, accelerates along a certain extent, facilitating the transport of the bubbles, which thus do not risk remaining trapped in the blood, and finally slows down again proximate to the vent, assuming the best conditions for the final separation of the bubbles, which leave through the vent.

[0020] If the amount of air bubbles present in the blood is modest, the described fluid-dynamics treatment can be sufficient to eliminate them completely. If instead the amount is considerable, the filtration membrane completes their elimination from the blood before the blood returns to the patient.

[0021] Blood filtration means 28 contained in region 12 comprises filtration membrane 16, which is supported by annular frame 17. As best seen in Figure 6, where a portion of the filtration membrane in removed, annular frame 17 comprises wire-like radial U-shaped bridges, such as 18, which extend monolithically from footing 19, which has a constant width. Blood flowing in either half-ring flow path must pass through filtration membrane 16 in order to flow from the inlet to the outlet of the arterial filter.

[0022] The blood, after passing through filtration

means 28, passes into lower collection chamber 13, (Figure 5) which is provided with outlet port 20 which is suitable to be connected to the arterial line of the extracorporeal circuit. The lower collection chamber has a constant width and a height which gradually increases from the inlet side of the arterial filter (at connector 10) to the outlet side of the arterial filter (at outlet port 20), to which the blood flow is directed by crest 21.

[0023] The described invention is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept. Thus, for example, the actual oxygenator, which in the described embodiment replicates the content of U.S. Patent No. 5,817,278 (Fini et al.), may be of any kind, including oxygenators having microporous hollow fiber bundles of various constructions, flat sheet microporous membranes, semi-permeable membranes, and other configurations and structures as known in the art.

[0024] The disclosures in Italian Patent Application No. MI2000A001852 from which this application claims priority are incorporated herein by reference.

[0025] Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

Claims

1. A device for oxygenating and filtering blood in an extracorporeal circuit comprising a housing defining first and second interior chambers, the first chamber containing a plurality of microporous filters and having a blood inlet and a blood outlet connected to the first chamber to define a blood flow path along an exterior of the hollow fibers and having a gas inlet and a gas outlet connected to the first chamber to define a gas flow path through the lumens of the hollow fibers, the second chamber containing a filtration membrane and having a blood inlet and a blood outlet connected to the second chamber to define a blood flow path through the filtration membrane, the blood inlet of the second chamber being connected to receive blood from the blood outlet of the first chamber.

2. An integrated device for oxygenating and filtering blood in an extracorporeal circuit, comprising:

   an oxygenator having a housing including a top, a bottom, and a side wall together defining an oxygenation chamber containing a microporous membrane, the housing having a blood inlet and a blood outlet positioned to define a blood flow path along a first side of the microporous membrane and a gas inlet and a gas outlet positioned to define a gas flow path along a second side of the microporous membrane; and

   an arterial blood filter having a housing including a top and bottom, a substantially cylindrical outer wall, and a substantially cylindrical inner wall together defining a substantially ring-shaped interior chamber containing a filtration membrane, the inner wall defining a substantially cylindrical opening in the housing of the arterial filter, the housing having a blood inlet connected to the interior chamber on a first side of the filtration membrane and a blood outlet connected to the interior chamber on a second side of the filtration membrane, to define a blood flow path through the filtration membrane, the blood inlet of the arterial filter being connected to the blood outlet of the oxygenator, the housing of the oxygenator being rigidly connected to the housing of the arterial filter and positioned in the substantially cylindrical opening in the housing of the arterial filter.

3. An integrated device for use in an extracorporeal blood circuit, comprising:

   a housing defining a first portion and a second portion;

   means for oxygenating blood contained within the first portion of the housing, the oxygenating means including a blood inlet and a blood outlet; and

   means for filtering oxygenated blood, the filtering means having a blood inlet connected to receive blood from the blood outlet of the oxygenating means and a blood outlet.

4. A monolithic device for use in extracorporeal blood circuit, comprising a housing having a blood oxygenator portion and an arterial blood filter portion, the blood oxygenator portion containing a gas exchange membrane and having a blood inlet and a blood outlet defining a blood flow path along a first side of the gas exchange membrane and having a gas inlet and a gas outlet for defining a gas flow path along a second side of the gas exchange membrane, the arterial blood filter portion containing a filtration membrane and having a blood inlet and a blood outlet defining a blood flow path through the filtration membrane, the blood inlet of the arterial blood filter portion being connected to receive blood from the blood outlet of the blood oxygenator portion.

5. An arterial blood filter comprising:

   a housing having a top surface, a bottom sur-

face, a substantially cylindrical outer wall and a substantially cylindrical inner wall together defining a substantially ring-shaped interior chamber, the inner wall defining a substantially cylindrical opening from the top surface to the bottom surface of the housing;
a filtration membrane contained within the ring-shaped interior chamber;
a blood inlet; and
a blood outlet, the blood inlet and blood outlet being positioned on the housing to define a blood flow path through the housing across the filtration membrane.

Fig. 1

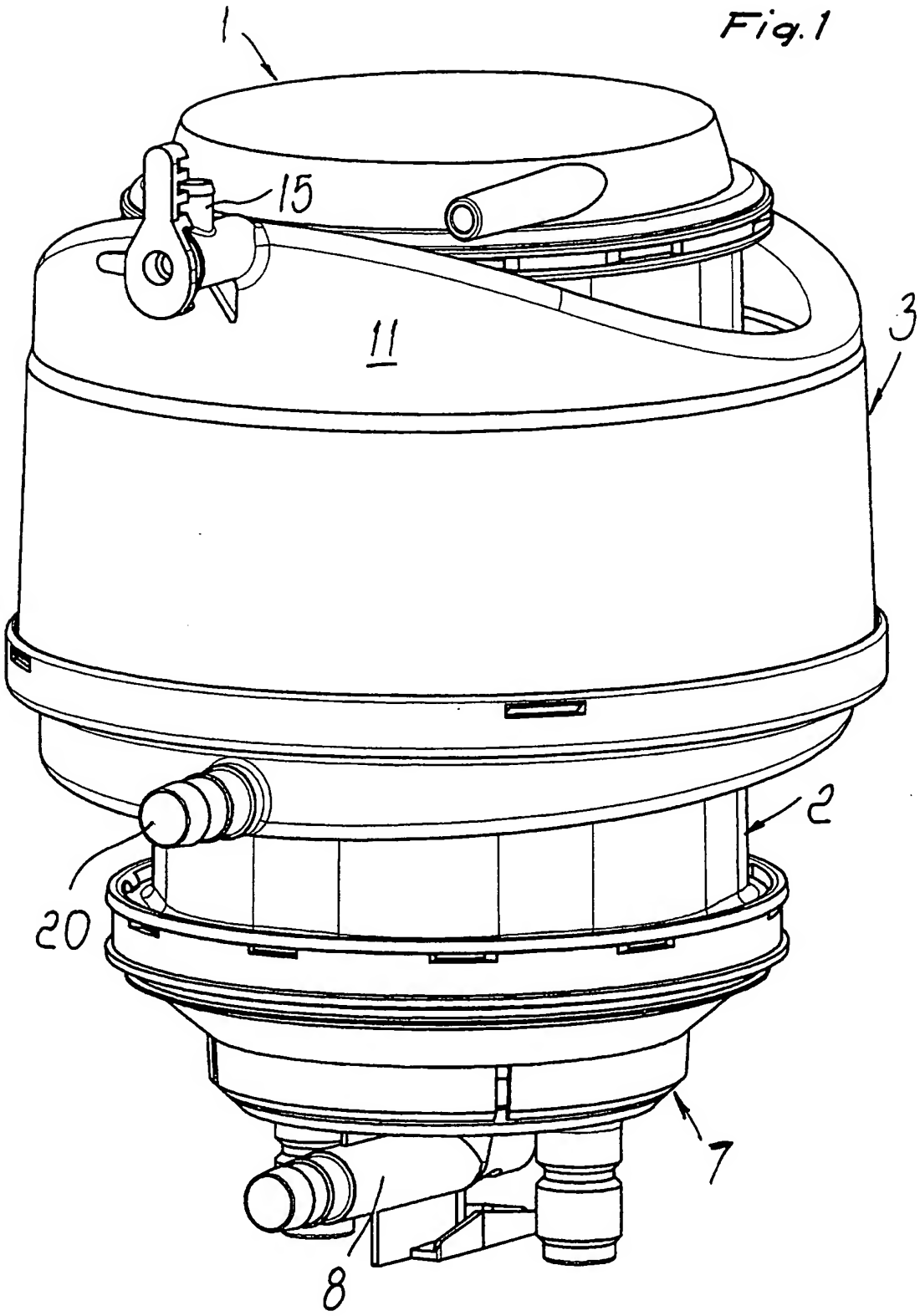


Fig.2

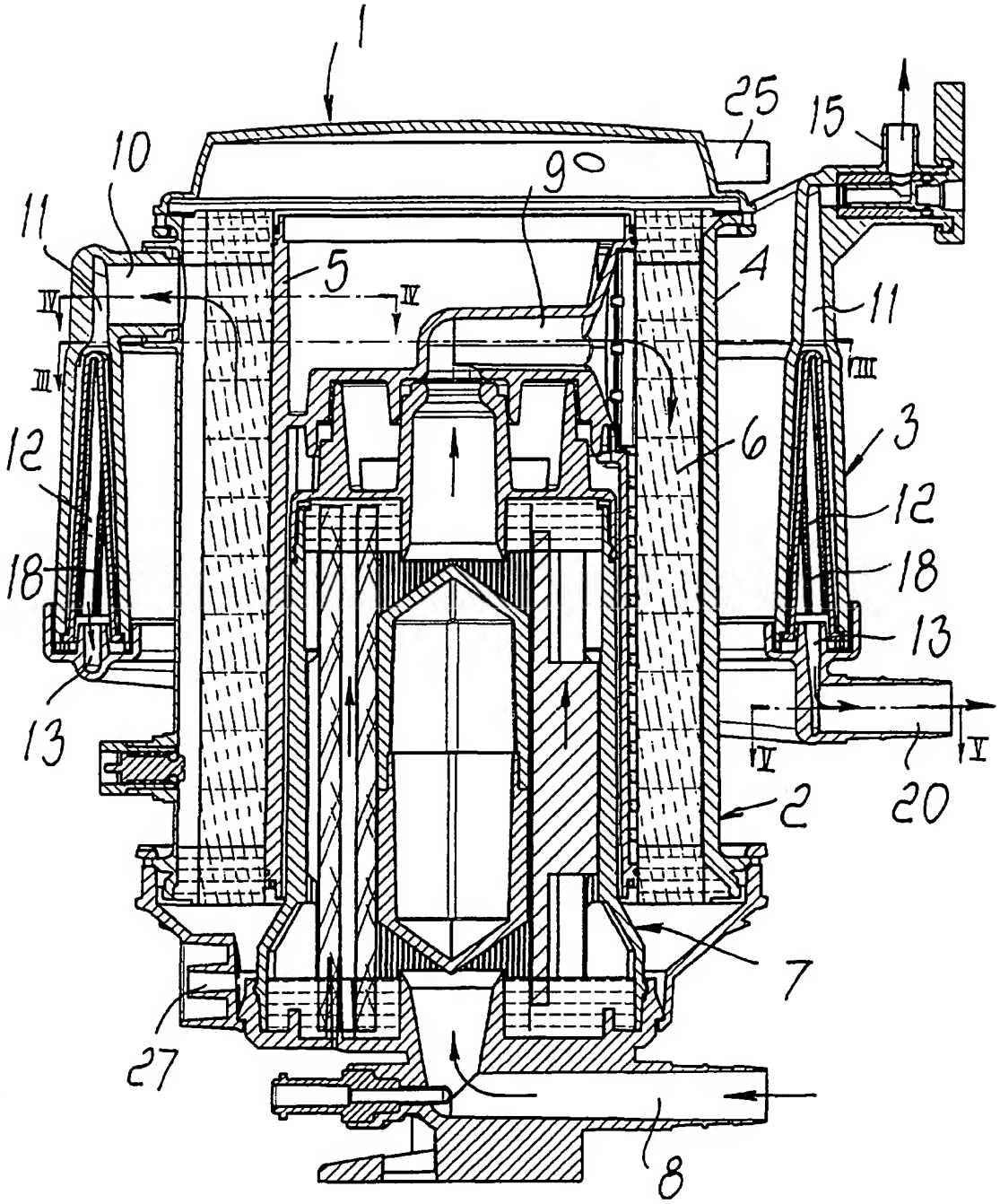


Fig. 3

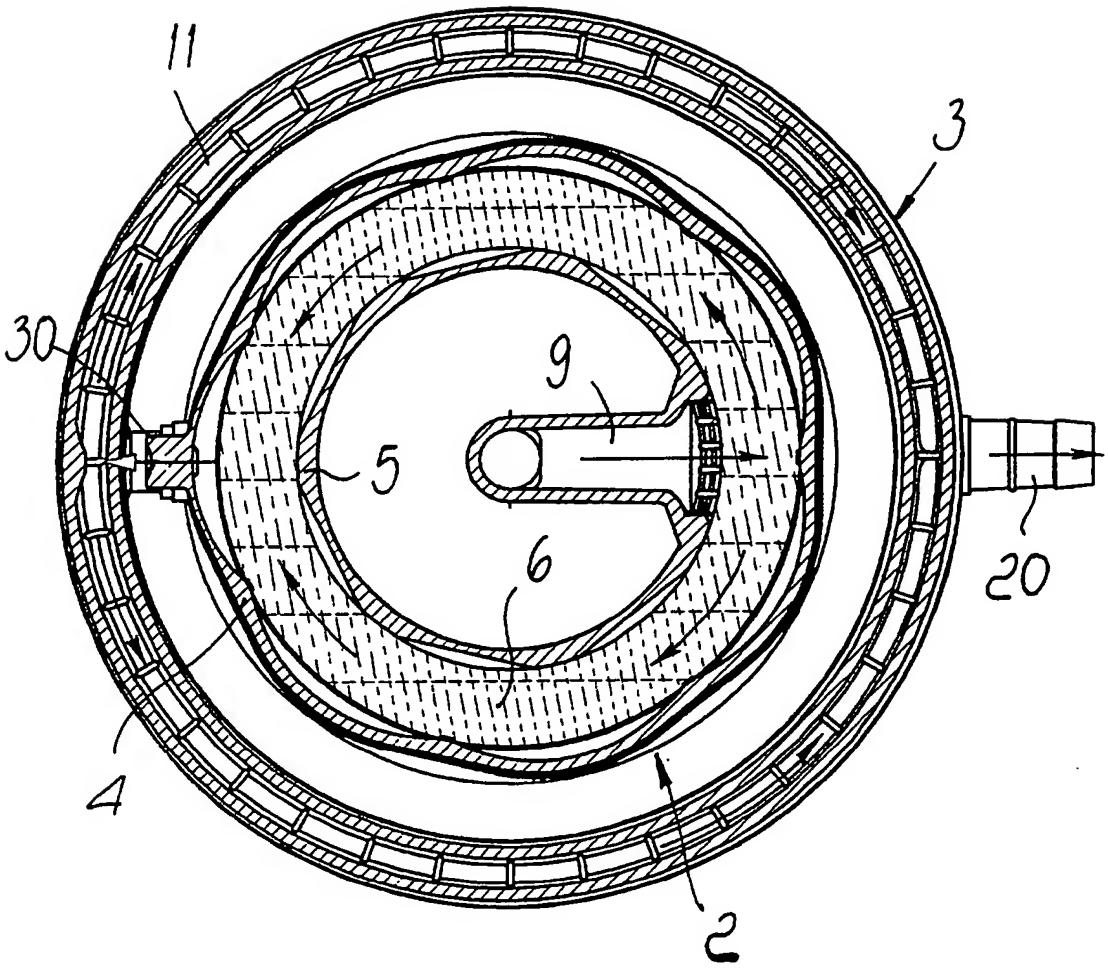


Fig.4

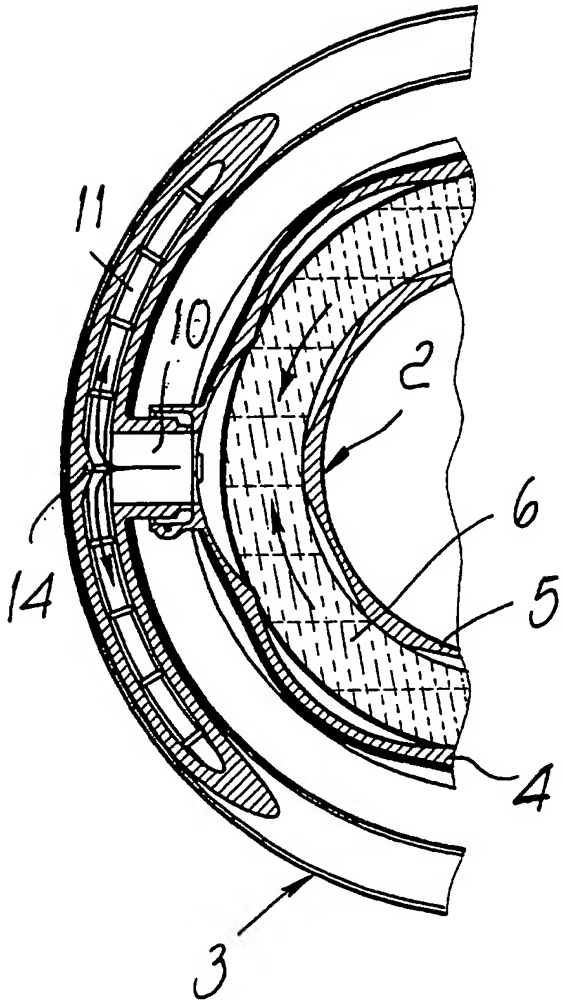


Fig.5

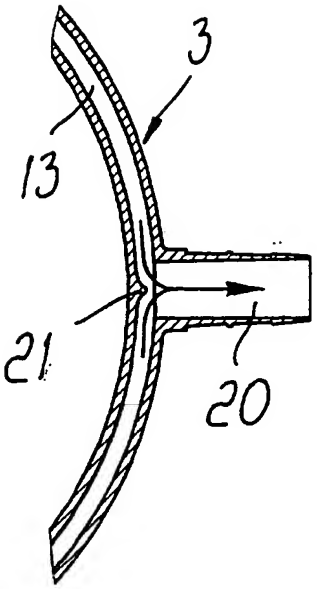


Fig. 6

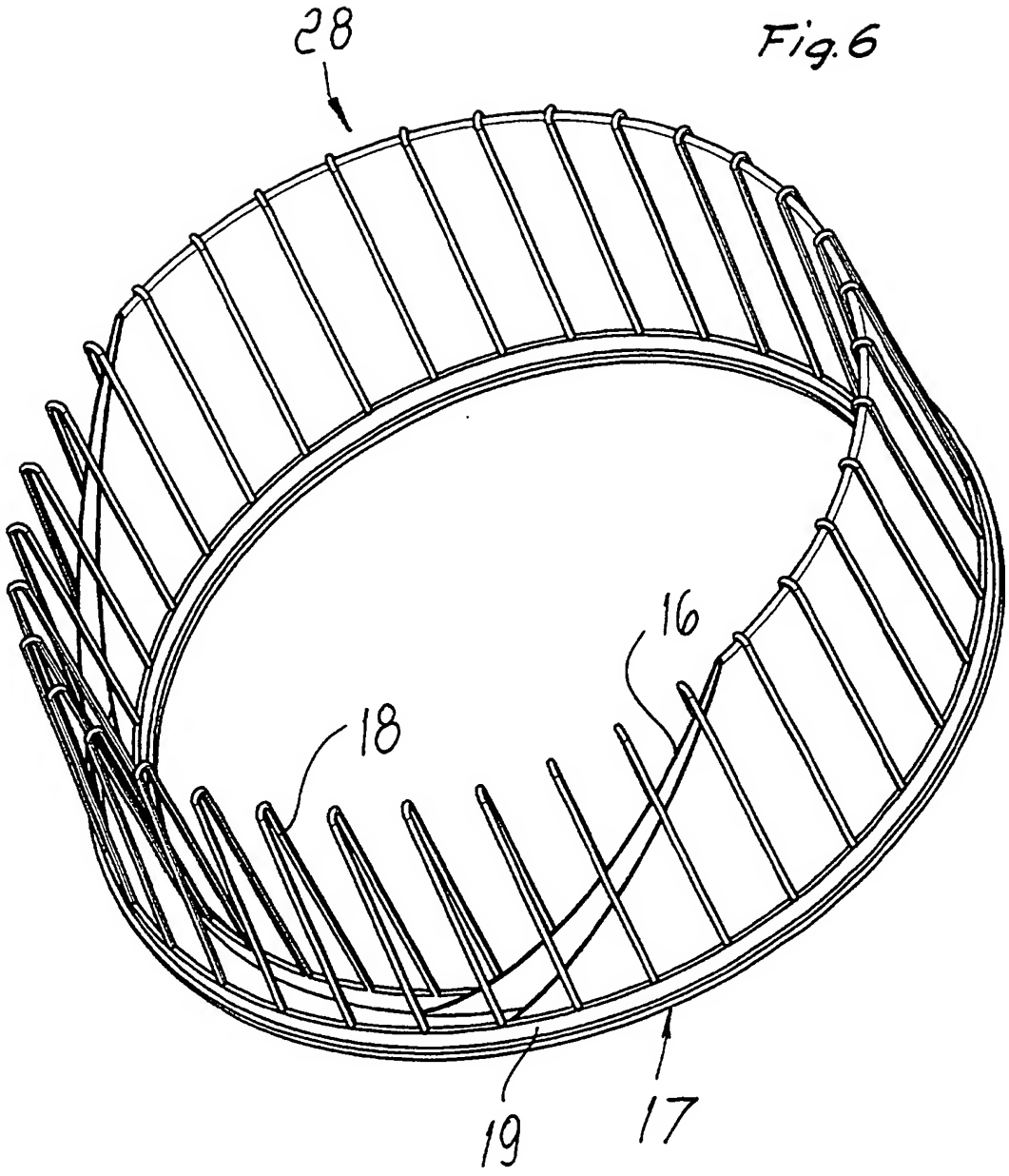


Fig. 7

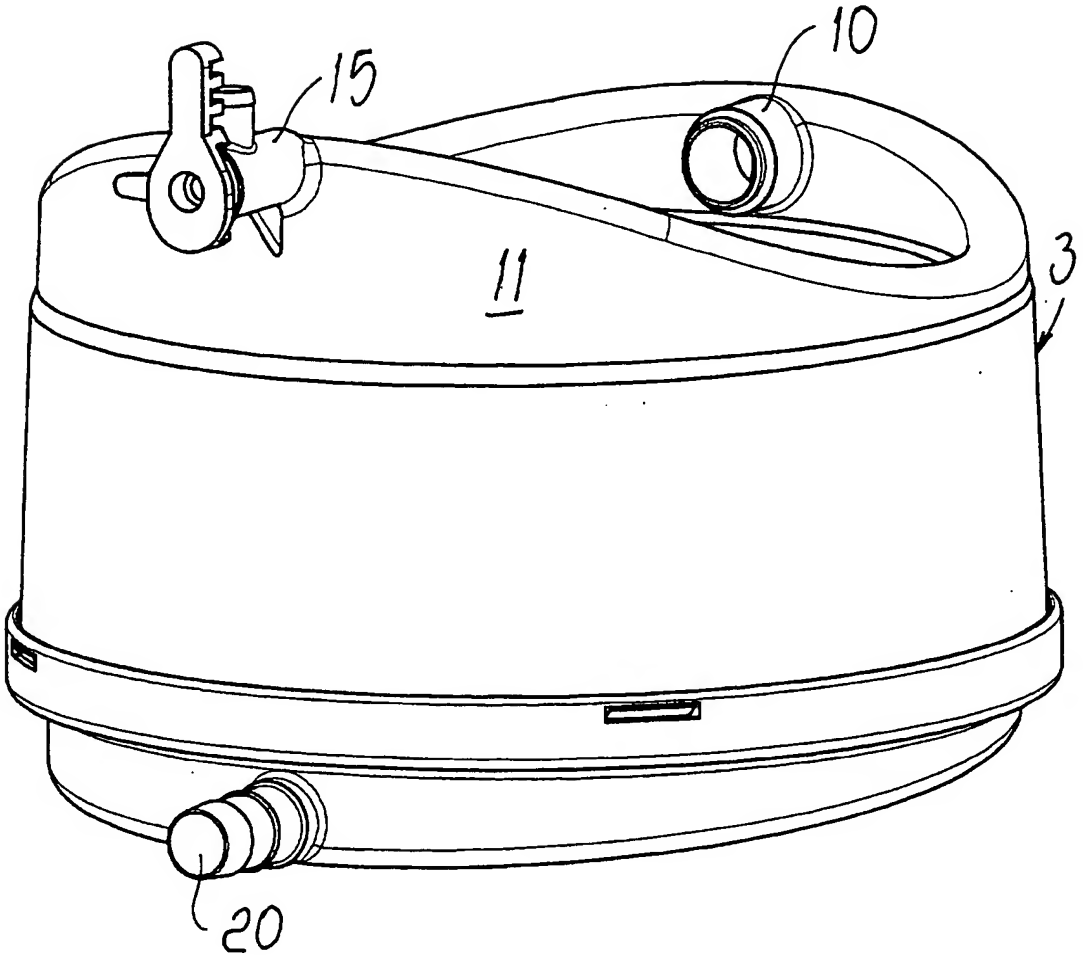
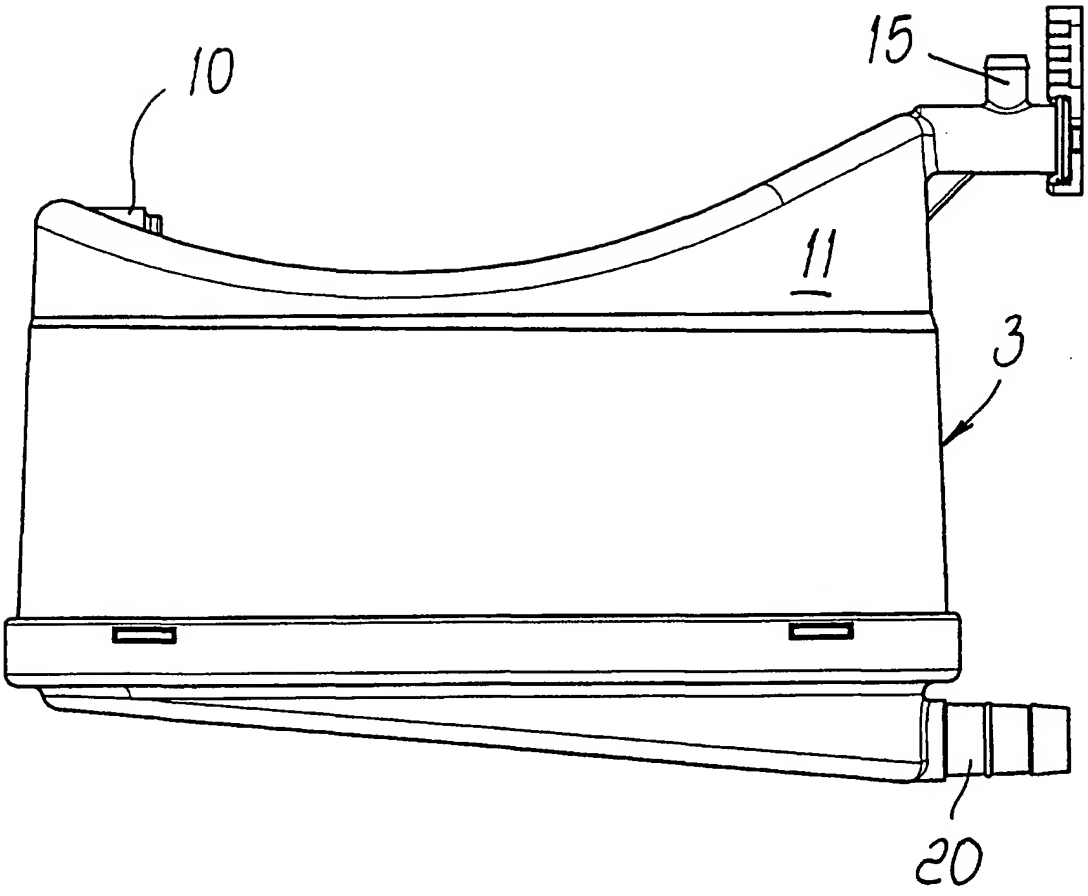


Fig. 8



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 01 11 8731

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 762 868 A (LEONARD RONALD J) 9 June 1998 (1998-06-09)	1,3,4	A61M1/00 A61M1/16
A	* abstract; figures 5,6,7,7A * * column 1, line 41-49 * * column 1, line 59 - column 2, line 36 * * column 3, line 31-39 * * column 4, line 43 - column 6, line 36 * * column 8, line 43 - column 9, line 20 * * column 9, line 40 - column 10, line 7 * * column 10, line 26-67 *	2,5	B01D63/00 B01D63/02 A61M1/10 A61M1/36
X	EP 0 089 122 A (CORDIS DOW CORP) 21 September 1983 (1983-09-21)	1,3,4	
A	* abstract; figures 1-3,11 * * page 13, line 18-23 *	2,5	
X	US 5 034 188 A (ISHII SHUICHI ET AL) 23 July 1991 (1991-07-23)	5	
A	* abstract; figures 1-3 * * column 4, line 60 - column 7, line 20 *	1-4	
X	EP 0 371 173 A (BAXTER INT) 6 June 1990 (1990-06-06)	5	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61M
A	* abstract; figures * * column 2, line 35-38 * * column 2, line 52 - column 3, line 1 * * column 3, line 22-31 * * column 3, line 36 - column 4, line 14 * * column 4, line 55 - column 5, line 1 * * column 5, line 15 - column 6, line 2 * * column 6, line 30 - column 7, line 42 * * column 8, line 20 - column 9, line 50 *	1-4	B01D
A	US 5 770 149 A (RAIBLE DONALD A) 23 June 1998 (1998-06-23) * abstract; figures 9,9A * * column 12, line 55 - column 13, line 40 *	1-5	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
MUNICH	16 November 2001	Lager, J

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 01 11 8731

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	EP 0 320 815 A (DIDECO SPA) 21 June 1989 (1989-06-21) * abstract; figure 1 * * column 2, line 32-36 *	1-5	
A,D	US 5 817 278 A (GHELLI NICOLA ET AL) 6 October 1998 (1998-10-06) * abstract; figures *	1-5	
A	EP 0 713 709 A (DIDECO SPA) 29 May 1996 (1996-05-29) * abstract; figures *		

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
MUNICH	16 November 2001	Lager, J

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 01 11 8731

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

16-11-2001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5762868 A	09-06-1998	AT 190227 T	15-03-2000
		DE 69607038 D1	13-04-2000
		DE 69607038 T2	16-11-2000
		EP 0876171 A1	11-11-1998
		JP 2000501954 T	22-02-2000
		WO 9719714 A1	05-06-1997
EP 0089122 A	21-09-1983	AT 35621 T	15-07-1988
		AU 565652 B2	24-09-1987
		AU 1114383 A	25-08-1983
		BR 8300807 A	16-11-1983
		CA 1190443 A1	16-07-1985
		DD 207656 A5	14-03-1984
		DE 3377331 D1	18-08-1988
		DK 71283 A ,B,	20-08-1983
		EP 0089122 A2	21-09-1983
		JP 1814216 C	18-01-1994
		JP 5020111 B	18-03-1993
		JP 58155862 A	16-09-1983
		NO 830578 A ,B,	22-08-1983
		NZ 203283 A	08-11-1985
US 5034188 A	23-07-1991	NONE	
EP 0371173 A	06-06-1990	EP 0371173 A1	06-06-1990
US 5770149 A	23-06-1998	WO 9716213 A2	09-05-1997
EP 0320815 A	21-06-1989	IT 1223470 B	19-09-1990
		AT 102056 T	15-03-1994
		AU 605399 B2	10-01-1991
		AU 2834189 A	19-07-1990
		CA 1308320 A1	06-10-1992
		DE 3888120 D1	07-04-1994
		DE 3888120 T2	09-06-1994
		EP 0320815 A2	21-06-1989
		ES 2049241 T3	16-04-1994
		US 5039482 A	13-08-1991
US 5817278 A	06-10-1998	IT 1271104 B	26-05-1997
		AT 205733 T	15-10-2001
		DE 69522780 D1	25-10-2001
		EP 0713709 A2	29-05-1996
EP 0713709 A	29-05-1996	IT 1271104 B	26-05-1997
		AT 205733 T	15-10-2001

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 01 11 8731

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

16-11-2001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0713709 A		DE 69522780 D1	25-10-2001
		EP 0713709 A2	29-05-1996
		US 5817278 A	06-10-1998

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82